

06-1606

T.F.W.

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

5

Application Number

10/564,441

Filing Date

January 12, 2006

First Named Inventor

Persson et al

Art Unit

1645

Examiner Name

Attorney Docket Number

SSI7USA

**ENCLOSURES**

(Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	15-Documents
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

Remarks

Customer No. 00270

Express Mail No. ED379414225US

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name

HOWSON AND HOWSON

Signature

Printed name

Cathy A. Kodroff

Date

June 15, 2006

Reg. No.

33,980

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

Typed or printed name

Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Express Mail No. ED379414225US

Customer No. 00270



SSI7USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/564,441 Confirmation No.: 7400  
Applicant : Persson et al  
Filed : January 12, 2006  
TC/A.U. : 1645  
Examiner :  
Customer No. : 00270  
Title : DIAGNOSTICS OF DIARRHEAGENIC ESCHERICHIA COLI  
(DEC) AND SHIGELLA SPP.

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08B is attached and copies of the documents are enclosed herewith. This Information Disclosure Statement is submitted more than three months from the filing date of this application and before the receipt of a first Office Action on the merits. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Express Mail No. ED379414225US

### REMARKS

The month of publication for documents (B), (C), (F), (I), (J) could not be determined. The years of publication for these documents are sufficiently earlier than the effective US filing date and/or the foreign priority date of the present application so that the particular month of publication of the documents is not in issue (MPEP 609).

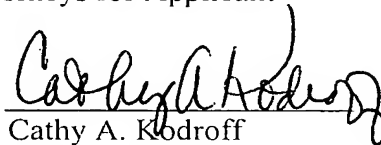
Item (I) is a non-English document and Item (J) provides an English summary. This document describes the significance of E. coli of two O-groups in the etiology of infant diarrhea.

The Examiner is respectfully requested to consider the enclosed document identified in this paper and in the attached Form PTO/SB/08B during the course of examination of this application.

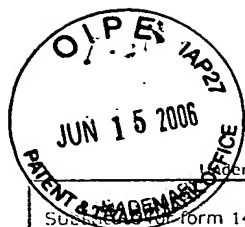
Respectfully submitted,

HOWSON AND HOWSON  
Attorneys for Applicant

By



Cathy A. Kodroff  
Registration No. 33,980  
501 Office Center Drive  
Suite 210  
Fort Washington, PA 19034  
Phone: (215) 540-9200  
Fax: (215) 540-5818



PTO/SB/08B (08-C3)  
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Submit this form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	2	Attorney Docket Number	SSI7USA
-------	---	----	---	------------------------	---------

### Complete if Known

Application Number	10/564,441
Filing Date	January 12, 2006
First Named Inventor	Persson et al
Group Art Unit	1645
Examiner Name	

### NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	A	BASTIAN ET AL, Comparison of 14 PCR Systems for the Detection and Subtyping of stx Genes in Shiga-Toxin-Producing Escherichia Coli, Res. Microbiol., 149,(7), pp. 457-472, (July-August 1998)	
	B	BRAY J., Isolation of Antigenically Homogeneous Strains of Bact. Coli Neapolitanum From Summer Diarrhoea of Infants, The Journal of Pathology and Bacteriology, Vol. LVII, No. 2, pp. 239-247, (1945)	
	C	BRAY J., Slide Agglutination of Bacterium Coli Var. Neapolitanum in Summer Diarrhoea, The Journal of Pathology and Bacteriology, Vol. LX, No. 3, pp. 395-401, (1948)	
	D	INOUE ET AL, Amino Acid Sequence of Heat-Labile Enterotoxin from Chicken Enterotoxigenic Escherichia Coli is Identical to that of Human Strain H 10407, FEMS Microbiology Letters 108, pp. 157-162, (April 1993)	
	E	JOHNSON WM ET AL, Cytotoxic Escherichia Coli 0157:H7 Associated With Haemorrhagic Colitis in Canada, The Lancet, 1; 1(8314-5:76, (January 1983)	
	F	KAPER, J.B., Defining EPC, Rev. Microbiol. Sao Paulo 27:130-133, (1996)	
	G	KAUFFMANN F., The Serology of the E. Coli Group, J. Immunol. 57, No. 1, pp. 71-100, (September 1947)	
	H	LEVINE MM., Escherichia Coli that Cause Diarrhea: Enterotoxigenic, Enteropathogenic, Enteroinvasive, Enterohemorrhagic, and Enteroadherent, The Journal of Infectious Diseases, Vol. 155, No. 3, (March 1987)	
	I	ØRSKOV F., Nyt Nordisk Forlag. Arnold Busck. Escherichia Coli. Om Typebestemmelse, Specielt med Henblik pa Stammer Fra Infantil Diarrhoe. En Oversight, (1956)	
	J	ØRSKOV F., On The Occurrence of E. Coli Belonging to O-Group 26 in cases of Infantile Diarrhoea and White Scours, Separatum. Acta Pathologica. Vol. XXIX, Fasc. 4. (1951), [English version]	

Examiner Signature	Date Considered
--------------------	-----------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/564,441
				Filing Date	January 12, 2006
				First Named Inventor	Persson et al
				Group Art Unit	1645
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	SSI7USA

**NONPATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	K	SCHMIDT H., The Large-Sized Plasmids of Enterohemorrhagic Escherichia Coli O157 Strains Encode Hemolysins Which are Presumably Memebbers of the E. Coli Alpha-Hemolysin Family, FEMS Microbiol Lett., 1;117(2):189-96, (April 1994)	
	L	SEKIZAKI, T., Nucleotide Sequences of the Genes for Escherichia Coli Heat-Stable Enterotoxin I of Bovine, Avian, and Porcine origins, Am J. Vet. Res., Vol. 46, No. 4, (April 1985)	
	M	SETHABUTR, O., Detection of Shigellae an dEnteroinvasive Escherichia Coli by Amplification of the Invasion Plasmid Antigen H DNA Sequence in Patients with Dysentery, The Journal of Infectious Diseases, 167:458-61, (January 1993)	
	N	THOMAS, A., Non-radioactively Labelled Polynucleotide and Oligonucleotide DNA Probes, for Selectively Detecting Escherichia Coli Strains Producing Vero Cytotoxins VT1, VT2 and VT2 Variant, Molecular and Cellular Probes, 5, pp. 129-135, (April 1991)	
	O	WILLSHAW, G.A., Cloning of Genes Determining the Production of Vero Cytotoxin by Escherichia Coli, Journal of General Microbiology, 131, pp. 3047-3053, (Nov. 1985)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**